



IRB RESEARCHER MANUAL

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Overview of the IRB Protocol Module

Streamlyne’s IRB Protocol Module is designed to facilitate the review processes that ensure compliance with the federally-mandated protection of human subjects participating in research activities. Principal Investigators or Aggregators initiate and submit IRB protocols, amendments, and renewals within the system. Protocols are automatically routed to the IRB for review and approval.

Navigation and Common Elements

This guide assumes you are familiar with the common features and basic navigation as presented in the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements**. Please use that manual as a companion to this one, as we have tried to eliminate redundancy wherever possible.

The Action Symbols

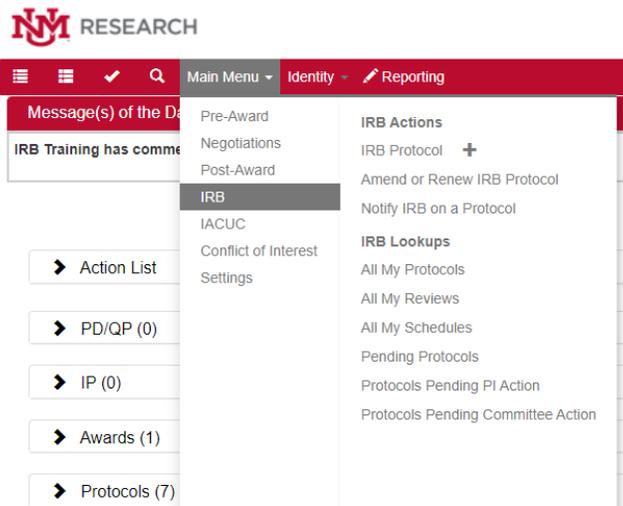
Streamlyne displays the type of Action required for each item in the second column on your Action List. Consult this table for definition and requirement for each Action symbol:

Symbol	Action	Requirement
	Acknowledge	This item requires your acknowledgement in order for the document to move forward in its process.
	Approve	This item requires that you review the details and decide to Approve, Disapprove, or Reject the document’s contents.
	Complete	This item requires that you complete one or more sections of the document in order for the document to move forward in its process.
	For Your Information	This item is being routed to you for informational purposes only.

Searching with IRB Lookups

To assist you in locating IRB Protocols within Streamlyne, IRB search windows, called lookups, are available from the Main Menu. Access to these lookups depends on the IRB roles assigned to you in your Person record, or user profile. Most users at an institution will have the necessary permissions to prepare and submit a protocol, while only IRB administrators will have access to the various administrative functions related to IRB protocols and committees. Some users (such as Department Chairs or IRB Committee Members) may also be involved in approving or reviewing protocols. See **Appendix A: IRB Roles and Permissions** for a complete list.

To search for items using IRB lookups, simply navigate from the Main Menu to the corresponding IRB Lookup as indicated below. Results will be displayed at the bottom of the page. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button. If a search did not find the information you are searching for the asterisk symbol (*) acts as a wildcard to give you flexibility in searching. Use the wildcard symbol in any field on a Lookup that will accept a hand-keyed value. Example: *search value.



All My Protocols

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

This lookup will generate a list of all the protocols you have ever submitted and any protocols where you are listed as personnel, regardless of the document status. If you are not the Principal Investigator or do not have permissions to edit the document, you will only be able to view the protocol document.

Pending Protocols

Navigation

Main Menu > IRB > IRB Lookups > Pending Protocols

This lookup will generate a list of protocols that are in various statuses pending approval. The search results will include any protocols where you are listed as personnel. If you are not the Principal Investigator or do not have permissions to edit the document, you will only be able to view the protocol document.

Protocols Pending PI Action

Navigation

Main Menu > IRB > IRB Lookups > Protocols Pending PI Action

This lookup will generate a list of protocols that are pending action from the Principal Investigator. Typically, these are protocols that have been returned to the PI for revisions. The search results will include any protocols where you are listed as personnel. If you are not the Principal Investigator or do not have permissions to edit the protocol, you will only be able to view the protocol document.

Protocols Pending Committee Action

Navigation

Main Menu > IRB > IRB Lookups > Protocols Pending Committee Action

This lookup will generate a list of protocols that have been submitted and are awaiting Committee review and approval. The search results will include any protocols where the user is listed as personnel. If you are not the Principal Investigator or do not have permissions to edit the document, you will only be able to view the protocol document.

For Investigators and Other Protocol Preparers (Aggregators)

The second section provides a step-by-step guide to prepare, submit, and follow up on an IRB Protocol in Streamlyne.

Initiating & Submitting a New Protocol

This section will describe the steps to initiate and submit a new IRB Protocol in Streamlyne Research. Principal Investigators (PIs), other researchers or their support staff initiate and submit these documents. If you will be initiating or submitting IRB protocols, use this section to begin using the IRB module productively. For a flowchart of the standard lifecycle of a protocol, see [Appendix B: IRB Protocol Workflow Overview](#).

Initiating a New IRB Protocol

If your goal is to quickly initiate and save a protocol for later editing, be sure to have the following information available, as these four fields must be completed for the document to save without validation errors:

Tab	Section	Field Name	Description	Instructions
Protocol	Required Fields for Saving	Protocol Type	Differentiates the type of protocol. Defaults to Minimal Risk	Select one from dropdown: Minimal Risk, More than Minimal Risk, IRB Review Not Required Determination, Request for External IRB Review.
Protocol	Required Fields for Saving	Principal Investigator (Internal User Name Search)	Person ID of the investigator leading the human research activities recorded in the IRB protocol.	Use the magnifying glass to look up and select return value of the appropriate ID.
Protocol	Required Fields for Saving	Title	Full project title	Enter freeform text.

Tab	Section	Field Name	Description	Instructions
Protocol	Required Fields for Saving	Lead Unit	Unit ID of the department leading the project.	If the PI is a UNM employee, the Lead Unit field <u>automatically</u> populates with their assigned Unit ID. If this is not the correct value, click the magnifying glass to look up and select return value of the appropriate Unit ID.

Navigation	Main Menu > IRB > IRB Actions > IRB Protocol > +
-------------------	---

To quickly initiate and save a Protocol, follow these steps:

1. Initiate a new document by following the navigation path above.
2. Complete the Minimum Required Fields for Saving detailed in the preceding table.
3. Click the Save button. 

Result A protocol number is automatically assigned. This protocol number will be visible at the top right of the screen.

Note Once the document is saved, it will remain on your Action List as a pending item with a COM (complete) symbol, prompting you to complete the document at your convenience. The protocol will remain on your Action List as a COM pending item until you submit it, delete it, or withdraw it. Access the IRB Protocol again by clicking on the corresponding Id hyperlink next the COM item on your Action List.

Updating the Protocol Tab > Required Fields for Saving Document

Required Fields for Saving Document

Required Fields for Saving Document

* Protocol Type : 1-Minimal Risk

1-Minimal Risk
2-More than Minimal Risk
3-IRB Review Not Required Determination
4-Request for External IRB Review

* Principal Investigator : Internal User Name Search

External Address Book Search

* Title :

* Lead Unit : select

1. The **Protocol Type** is used to designate the level of IRB review required, a request for an IRB Review Not Required Determination, or a request for deferral to an External IRB. Click the arrow next to the **Protocol Type** field, and then select the appropriate option from the dropdown list.
2. Look up the internal or external user serving as **Principal Investigator** by clicking the magnifying glass  to search for and select return value of the desired record.
3. Enter a descriptive title for the project in the **Title** field.
4. The **Lead Unit** defaults to the department assigned to the Principal Investigator. If this is not the correct department for the project, enter the Unit Number into the **Lead Unit** field. If necessary, use the dropdown to select the correct value. Only Units associated with the PI and/or the protocol Initiator will be offered.
5. Click the Save button. 

Result Streamlyne will generate a Protocol Number that will display in both the Document Header and the Status & Dates section. The protocol number is ten digits in length. The first two digits represent the year of the creation date, the next two digits represent the month of the creation date, and the remaining six digits are assigned sequentially, as follows:
YYMM123456.

The Initiator and Last Updated timestamp will be updated in the Document Header as well:

Document Number : 8036	Document Status : Submitted to IRB
Initiator:Last Updated : vflint@unm.edu : 01:46 PM 04/21/2022	Submission Status : Pending
Protocol # : 2204001979	Expiration Date :

Protocol Tab > Statuses & Dates

▼ Status & Dates

Status & Dates ⓘ

Protocol # : 2204001979	Protocol Status : Submitted to IRB
Approval Date : Generated on Approval	Last Approval Date : Generated on Renewal Approval
Initial Submission Date : 04/21/2022	Expiration Date : Generated on Approval

This panel above contains read-only data recording milestones in the lifecycle of the protocol along with routinely referenced information such as Protocol # and Protocol Status.

Protocol Tab > Additional Information

▼ Additional Information

Additional Information ⓘ

FDA IND or IDE # :

IRBNetID: ClinicalTrials.gov ID:

Summary/Keywords :

The panel above is used to track identifiers related to the work performed on the project. Available fields include FDA IND or IDE#, IRBNet ID (legacy studies only) and Clinical Trials.gov ID. If your project originated in IRBNet, the original IRBNet reference # will be auto populated for your reference. These identifiers will not apply to every protocol.

Protocol Tab > Additional Information > Other Identifiers

The Other Identifiers subsection is specifically intended to capture alternate protocol numbers for this project. If this project has been deferred to and has a protocol number with an external IRB, capture important information in this section. This will not apply to every protocol.

	* Type	* Other Identifier	Application Date	Approval Date	Actions
add:	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Add"/>

1. If this project is associated with an external IRB, click the arrow next to the **Type** field and select External IRB from the drop-down list.
2. Enter the IRB number assigned by the external organization in the **Other Identifier** field.
3. Populate the **Application Date** and/or the **Approval Date** in MM/DD/YYYY format or click the calendar icon  to select the date.
4. Provide the name of the IRB of record in the **Comments** field.
5. Click the Add button to add the entry to the protocol.

Protocol Tab > Organizations

DO NOT USE. This section is not used by the UNM IRB. External research site information is collected in the IRB New Questionnaire form.

Protocol Tab > Funding Sources

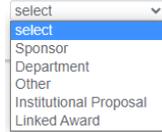
The Funding Sources section internally links the protocol to one or more proposals, awards, or departments within Streamlyne Research.

	* Funding Type	* Funding Number	* Source	Title	Actions
Add:	<input type="text" value="select"/>	<input type="text"/>	<input type="text"/>		<input type="button" value="Add"/>

1. Click on the header to expand the Funding Sources section.



2. Click the arrow next to the **Funding Type** field to select the source from the dropdown list.



Note Because UNM is using the Streamlyne Research Pre-Award and Post-Award suites, the **Funding Number** field dynamically integrates to these modules facilitating congruency checks.

If you selected a Funding Type of Sponsor, Department, Institutional Proposal, or Linked Award, Streamlyne will prompt you to link the specific document to the Protocol using the magnifying glass next to the **Funding Number** field to search for and select the desired value.

If your funding is coming directly from a Sponsor or a Department/Unit within your institution, Streamlyne will prompt you to identify the Sponsor or Unit instead of a Funding Number.

Entering this information will also display the Institutional Proposal and/or Award on the Streams page for easy access between different administrators who need to view the linked documents (if permissions allow).

3. Enter a **Funding Number** or click the magnifying glass  to search for and select the corresponding return value.

4. Click the Add button to complete this action.



5. Repeat Steps 2 through 4 until all Funding Sources are identified.

Updating the Personnel Tab

1. To identify protocol personnel in addition to the Principal Investigator, click on the tab header to access the Personnel tab.



- For UNM affiliated personnel, click the radio button next to either **Internal User Name ID**. You may enter the Last Name and click the magnifying glass.

You can also search for a person by clicking the magnifying glass  to look up the **Internal User Name** or **External Address Book ID** (non-UNM research personnel).

- Click the arrow next to the **Protocol Role** field to select the team member's role from the dropdown list.

- Click the Add button to complete this action.

Result A new section will be created for each person with subsections for Person Details, Contact Information, Attachments and Unit Details.

- Click the section header to expand the user section.

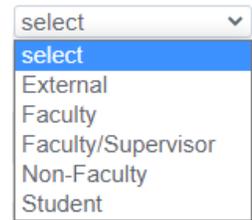
- Click the Show button to expand the Person Details subsection.



7. Click the arrow next to the **Protocol Role** field to edit if necessary.

8. Click the arrow next to the **Affiliation Type** field to select the appropriate affiliation from the list.

Note: If Student is selected, a Faculty/Supervisor must also be identified.

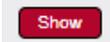


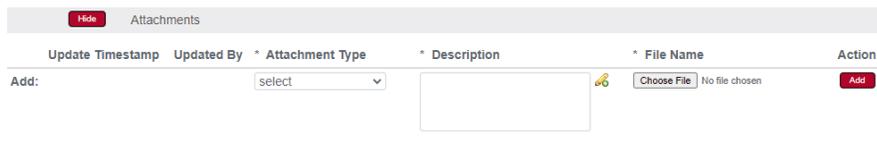
9. Click the Show button to expand the **Training**. 

10. If the individual has completed the CITI UNM Main Campus Researchers training, the information will appear here. If the training is expired or no training is noted, have the individual complete the training. The information will automatically appear the following calendar day.

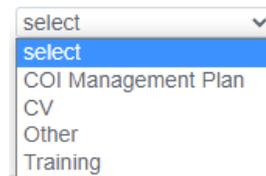
11. Click the Show button to expand the **Contact Information**. This information feeds into Streamlyne through UNM Banner. 

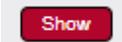
12. Update defaulted contact information if necessary.

13. If you need to attach personnel-specific documents, click the Show button  to expand the Attachments subsection. This is where COI Management Plan and CV would be uploaded, if applicable.



14. Click the arrow next to the **Attachment Type** field to select the appropriate attachment type from the list. Your institution may configure the selections in the dropdown.



15. Enter a description for the attachment in the **Description** field.
16. Click the Browse button to access files on your computer. Follow your operating system's prompts.
17. Click the Add button  to add the Attachment.
18. Click the Show button  to expand the Unit Details subsection.

Unit Details			
	Unit/Department Name	* Unit Number	Actions
Add:	(select) 	<input type="text"/>	
1	University of New Mexico	000001	

19. Click the magnifying glass  to search for an additional Unit or enter the unit number in the **Unit Number** field if you know it. Adding additional units is rarely necessary.
20. Click the **Lead** box to indicate if this Unit is the lead unit for this investigator.
21. Click the Add button to add the Unit.
22. You can click the Delete button to remove a Unit if entered in error.
23. Repeat these steps until all personnel are identified and the appropriate information is added.

Note If you find that you have added a team member in error, simply click the checkbox on the section header, and then click the Delete Selected button at the bottom of the page.

Updating the Questionnaire Tab

The Questionnaire functionality in Streamlyne allows Principal Investigators to provide required information at the time of submission. The particular questions presented to the user are also dependent on whether you are submitting a New Protocol, Amendment or Renewal.

1. Click on the tab header to access the Questionnaire tab.
2. Click on the section header to expand the Questionnaire section.

A dark red rectangular button with the word "Questionnaire" in white text.A dark red rectangular button with a white right-pointing arrow followed by the text "IRB New Questionnaire (Incomplete)" in white.

3. Read each item carefully and provide a response. Enter detailed descriptions or explanations where prompted. You may be directed to upload an attachment. Additional instructions on doing so can be found in the [Adding Notes & Attachments](#) section. NOTE: Additional questions may appear based on your answers.
4. Click the More Information button to the right of each question to review any Explanation, Policy or Regulation references where pertinent.
5. Click the Save button at any time to save your work.
6. The Questionnaire status will change to Complete once all questions are answered.

A light blue rectangular button with the text "More Information..." in blue.A dark red rectangular button with a white right-pointing arrow followed by the text "IRB New Questionnaire (Complete)" in white.

If the questionnaire is required, you will not be able to submit your protocol until all questions are answered and the Complete status displays.

Custom Data Tab

Please do not update any information in this section. This section contains customized fields of legacy and tracking data identified by UNM IRB.

Updating the Special Review Tab

The Special Review functionality is designed to record other reviews or administrative efforts linked to your IRB protocol in such instances as:

- Conflict of Interest reviews.

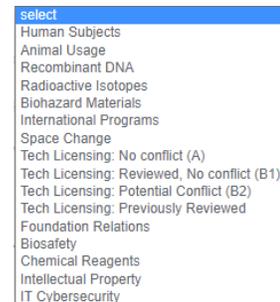
- Data sharing between projects that are tracked on separate IRB protocol documents.
- Technology/data protections for your project that are recorded on Intellectual Property Review documents.
- Biosafety, Radiation Safety and/or Environmental Health & Safety reviews.
- Research-related facilities requests or clearances for your projects, such as space requests, lab transfers or material handling requests.

Note If you add an IRB protocol that is also maintained in Streamlyne, these protocols will also show up in Streams for easy access between different users and administrators, per their permissions. All Special Review Types are determined by your institution.

1. Click on the tab header to access the Special Review tab.



2. Click the arrow next to the Special Review **Type** field to choose from the dropdown list.



3. The **Approval Status** field will auto-populate based on the protocol Status of the document whose Protocol Number you will identify in Step 4. Continue to the next step.

Otherwise, click on the arrow next to the **Approval Status** field to select the appropriate Approval Status from the dropdown list.

4. Click the magnifying glass  next to the **Protocol Number** field to look up this value.
5. Enter the **Application Date**, **Approval Date**, and **Expiration Date** of your linked project, if known. Type these values in MM/DD/YYYY format or click the calendar icon  to select the date.

6. Click the Add button to complete this action.
7. Repeat Steps 2 through 7 until all related reviews are recorded.

Note Only fields marked with an asterisk (*) are required.

Updating the Permissions Tab

The Permissions tab contains read-only user role and project role data for the personnel identified in the previous sections. For example, the protocol’s default Aggregators (or editors) will be identified as the Principal Investigator and the Initiator (if different from the PI).

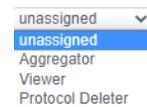
An Initiator can also grant access to ad hoc users who might not normally have access to protocol documents. This is especially useful to a researcher who would like to turn over Aggregating (editing) Rights to a coworker in an administrative support role. This feature is also commonly used to grant ad hoc Viewer Rights to users who do not normally have access to protocols.

1. Click on the tab header to access the Permissions section.
2. Scroll down to the Users section. If it is not already expanded, click on the header to expand the section.



Users						
Users						
	* User Name	Full Name	Unit #	Unit Name	Role	Actions
Add:	<input type="text"/>				unassigned	<input type="button" value="Add"/>
1	vflint@unm.edu	Valerie Crooker-Flint	798A	VP Resrch & Econ Devlpmnt VPRED	Aggregator PI	<input type="button" value="Edit Role"/>

3. If you need to add an ad hoc user, click the magnifying glass next to the **User Name** field to search for and select the correct value.
4. Click the arrow next to the **Role** field to select a permissions level for the ad hoc user.
5. Click the Add button to complete the action.
6. Repeat Steps 3 through 5 until all ad hoc users are added to the protocol.



- If you need to remove a user, click the Delete button.
- If you need to change the nature of a user's access to the protocol, click the Edit Role button next to the user's name. Otherwise, skip to the next section.

Edit Role

- Streamlyne will display a pop-up window listing the three permissions levels for a protocol.

Save

Indicate whether the user should have permissions to view the document, to aggregate (edit) document data, or to delete the document by

clicking the corresponding checkbox. Alternatively, you also have the option to remove defaulted or previously granted permissions by unchecking the corresponding boxes.

- Click the Save button to commit your changes.

Note The functionality of this section becomes more limited once the protocol is submitted into the IRB workflow. After submitting a document, the system limits Permissions changes to the addition of users with view-only privileges.

Adding Notes & Attachments

The Notes & Attachments section provides a place to track supporting documentation collected during the life of the protocol document.

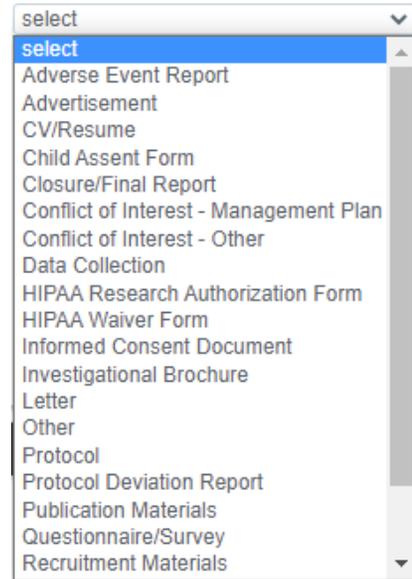
- Click on the tab header to access the Notes & Attachments section.

Notes & Attachments

- To upload an attachment, click on the Protocol Attachments header to expand the section. To add a Note only, skip to Step 11.

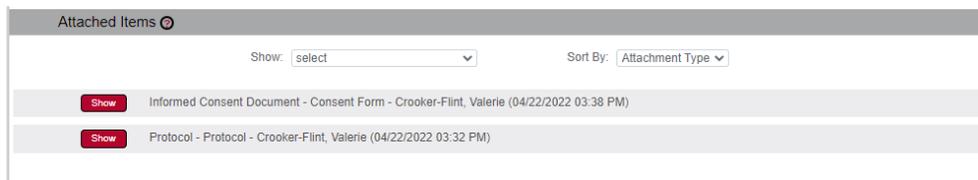
Protocol Attachments (0)

3. Click the arrow next to the **Attachment Type** field to select an appropriate option from the dropdown.



4. Describe the specific attachment in the **Description** field (e.g. Focus Group Consent, Online Survey Consent, Recruitment Email, Recruitment Flyer, Letter of Support, etc.).
5. Click the Browse button to access your operating system's Choose File or File Upload dialog box. Complete this action by following your operating system's prompts.
6. Click the Add button. 
7. Repeat Steps 3 through 8 until all attachments are added to the protocol.

Result The system compiles a list of attachments in the Attached Items subsection.



8. If you wish to view or update an attachment, click the Show button.
- You may then change the Status or edit the Description. You may also View, Replace or Delete the attached file.



Note The **Show** and **Sort By** fields can be used to filter or organize a long list of Attachments.

9. To enter a Note, click on the Notes header to expand the section.

Notes (0)



The screenshot shows a red header bar with a dropdown arrow and the text "Notes (0)". Below the header is a grey bar with "Notes" and a refresh icon. Underneath is a table with columns: "Created By", "Updated By", "* Note Topic", "* Note Text", "Restricted?", and "Actions". Below the table is an "Add:" label followed by a small text input field, a larger text area, a checkbox, and a red "Add" button.

10. In the **Note Topic** field enter a short description of what the note is about.
11. In the **Note Text** field enter or paste a complete note.
12. Click the **Restricted** checkbox if the Note should be restricted from users with View Only privileges.
13. Click the Add button  to add the Note to the database.
14. Repeat Steps 11 through 15 until all Notes are added.

Validating and Submitting a Protocol

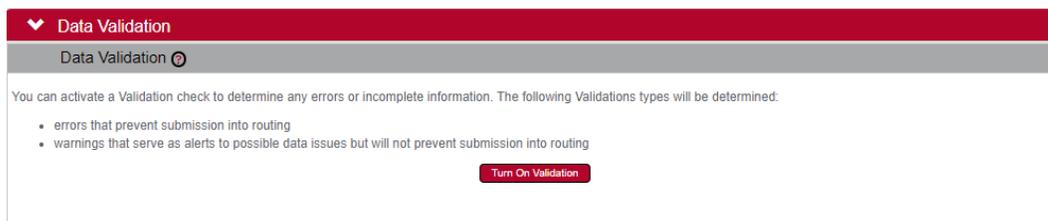
When a new protocol is complete, the Request an Action options available on the Protocol Actions tab include submitting the protocol for review or deleting the protocol. Data Validation is also available. These processes are defined in this section. A complete list of all available protocol actions is available in [Appendix C: All IRB Protocol Actions](#).

Validating the Protocol

1. Click the tab header to access the Protocol Actions tab.
2. Click the header to access the Data Validation section.

Protocol Actions

Data Validation



The screenshot shows a red header bar with a dropdown arrow and the text "Data Validation". Below the header is a grey bar with "Data Validation" and a refresh icon. The main content area contains the text: "You can activate a Validation check to determine any errors or incomplete information. The following Validations types will be determined:" followed by a bulleted list: "errors that prevent submission into routing" and "warnings that serve as alerts to possible data issues but will not prevent submission into routing". At the bottom of the content area is a red "Turn On Validation" button.

3. Click the Turn On Validation button. 
4. Streamlyne Research will run a series of validation steps to make sure all fields are populated correctly and that field entries do not conflict wherever possible. This same validation routine automatically runs when the protocol is submitted.

If errors are found, Streamlyne Research will display a red error message at the top of the page and display a list of errors found on the document.



If errors exist, click the Fix button  next to the first listed error.

Otherwise, skip to the next process.

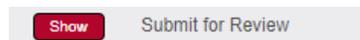
5. Streamlyne Research returns to the document section where the problem resides. Make your corrections and save the updated document.
6. Repeat Steps 4 and 5 as many times as necessary to resolve all errors.

Note This same validation routine is automatically run each time you submit the protocol into workflow. If it is the case that your submission is interrupted because of errors, you must resubmit the document by following the steps outlined in the very next process.

Submitting the Protocol to the IRB

Follow these steps to submit your protocol to the IRB. This submission action will enter the document into the IRB workflow. The workflow continues to the Office of the IRB for administrative pre-review followed by IRB Member or Committee review and final approval before research activities can begin. You can access the workflow status at any time via the Route Log.

1. Click on the tab header to access the Protocol Actions tab.
2. Click on the header to expand the Request an Action tab.
3. Click the Show button next to the Submit for Review option under the Available Actions subsection.



4. Streamlyne will display the Submit for Review subsection.

Click the arrows next to the **Submission Type** field and select the Initial Protocol Application for Approval option from the dropdown list.

Note If you are submitting an Amendment or Renewal these will show as options.

5. Click the arrow next to the **Submission Review Type** field to select the IRB submission type from the dropdown list, if known.



6. If you selected a **Submission Review Type** of Minimal Risk, Expedited – Federally Funded, or Exempt – Federally Funded in Step 5, you will be presented with predefined checklists, also known as Categories. All research procedures must fall under one or more Categories. Otherwise, selection Full Board and the OIRB will make the determination.

Note If you select the incorrect categories, this can be changed by IRB staff.

7. The **Type Qualifier** field will offer options in the dropdown based on **Submission Type** selected. If no dropdown options appear, skip to Step 8.

8. Click the Submit button  to send the IRB protocol into workflow.

Note If someone other than the PI submits a protocol, then the PI will be inserted as the first reviewer in workflow. The PI is required to approve the protocol before it is routed to the IRB workflow.

Note If you would like to confirm your submission was successful, verify that the Document Status in the Document Header has updated to Submitted to IRB.

Document Number : 32277	Document Status : Submitted to IRB
Initiator: Last Updated : irbadmin : 07:35 AM 07/18/2018	Submission Status : Pending
Protocol # : 1807002998	Expiration Date :

Understanding Available Actions after Initial Submission

There are approximately 15 actions that are conditionally available, depending on 1) where the protocol document is in its lifecycle; and 1) which actions were performed along the way. A complete list of all available protocol actions is in [Appendix C: All IRB Protocol Actions](#).

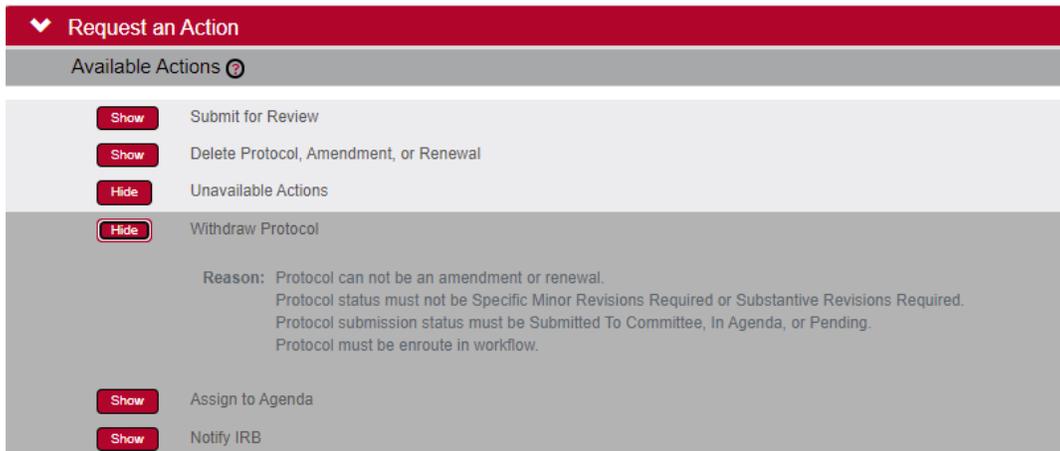
Available Actions

After initial submission, there are very few Available Actions for the user who has submitted the protocol. The Available Actions section will change over time as the protocol is reviewed, returned and eventually approved.

Note: If you would like to recall your protocol from the workflow for further edits, please see the [Recalling a Protocol](#) section.

Unavailable Actions

If you click the Show button next to any Unavailable Action you will be able to see the reason that Action is currently unavailable.



Recalling a Protocol

This action can only be performed after a document has been submitted into workflow and there are other users who need to approve the protocol before it is received by the IRB Analyst. This action will deliver the document back into Action List of the user who created/initiated the protocol. You can then make edits to the document and submit the document back into workflow. If your protocol has been submitted and you would like to recall the submission, follow these instructions to recall the document.

Note There is a similar function called Withdraw Protocol but this action is reserved for instances in which the protocol has already reached the IRB Analyst for review and approval and you no longer wish to have the protocol reviewed. Recall is used for instances in which you would like the protocol back for further edits before approvals and subsequent IRB review.

1. Click on the tab header to access the Protocol Actions tab.

Protocol Actions

2. Scroll to bottom of the page and click the Recall button.

Recall

Are you sure you want to recall this document to the action list?

* Please enter the reason below:

Yes Return to Document

3. Enter an explanation in the field provided.

4. If you are satisfied with your explanation continue to the next Step. Otherwise, click the Return to Document button to cancel the recall action.

5. Click the Yes button.

Note The Document Status and the Submission Status will be updated to Recalled in Routing.

Document Number : 32277	Document Status : Recalled in Routing
Initiator:Last Updated : irbadmin : 07:35 AM 07/18/2018	Submission Status : Recalled in Routing
Protocol # : 1807002998	Expiration Date :

Withdrawing a Protocol

If you have submitted an IRB protocol that has reached the IRB Analyst for review and approval, but you no longer wish to have it reviewed, you can use the Withdraw action to stop the approval and review process. Once the review process has begun, however, only the IRB Analyst will be able to withdraw the protocol.

1. Using Lookups, locate the protocol you would like to Withdraw.

2. Click the edit hyperlink.
3. Click on the tab header to access the Protocol Actions tab.
4. Click on the header to expand the Request an Action tab.
5. Click the Show button next to Withdraw Protocol.

Protocol Actions

Request an Action

Show Withdraw Protocol

Hide Withdraw Protocol

Withdrawal Reason :

Submit

6. Enter freeform text in the **Withdrawal Reason** field.
7. Click the Submit button to finalize your withdrawal.

Result The OIRB will be notified that the protocol has been withdrawn.

Note If you would like to proceed with review of this protocol in the future, you must create a new protocol document or use the copy function to reuse the information on the Withdrawn protocol.

Deleting a Protocol

If you initiate a Protocol, Amendment or Renewal, but then decide you will not be submitting it to the IRB after all, then follow these steps to delete the document from the system. This action can only be performed when a document has not yet been submitted. Please note that you will no longer be able to access this document and it will not be included in your list of protocols.

1. Within the Protocol, click on the tab header to access the Protocol Actions tab.
2. Click on the header to expand the Request an Action section.
3. Click the Show button next to Delete Protocol, Amendment, or Renewal.

Protocol Actions

Request an Action

Hide Delete Protocol, Amendment, or Renewal

Delete Reason :

Submit

4. Enter an explanation in the **Delete Reason** field.
5. Click the Submit button. 
6. Streamlyne will prompt you to confirm the action. Click the Yes button to confirm the deletion. The Protocol Status will be updated to Deleted.

Editing a Returned Protocol

A protocol may be returned to the Principal Investigator by the OIRB because it is incomplete, contains errors, or needs revisions based on IRB reviewer and/or committee feedback. Generally, a protocol is returned at two specific points in the process:

- When a **pre-review** has been conducted to vet protocols before assigning protocol reviews to committee members;
- **After formal IRB review**, when either a committee member or the full committee request specific minor or substantive revisions before approval can be granted.

The information available to the Principal Investigator and the manner in which they access the protocol document is influenced by the action taken by the OIRB to return the protocol. This section will describe the scenarios in which a protocol could be returned.

Accessing a Protocol Returned Before Committee Review (Pre-Review)

This first scenario occurs when the OIRB conducts a pre-review and sends the protocol document back to the PI using the Return to PI Action, as described in [Returning the Protocol to the PI](#). This option is only available before any type of formal IRB review has occurred.

Follow these steps when the title of the FYI Notification reads “Protocol Returned to PI Action,” as shown in the image here:

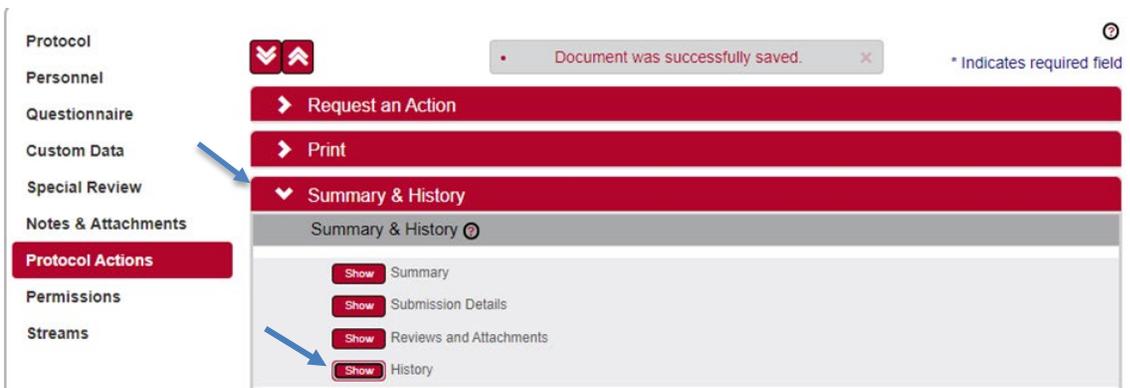
		8200	Streamlyne Research Notification	Protocol Returned to PI Action	FINAL		09:50 AM 04/26/2022	
---	---	------	----------------------------------	--------------------------------	-------	--	------------------------	--

1. When a protocol is returned to the PI through the Return to PI Action, Streamlyne will send two items to your Action List: An FYI Notification and a COM Notification, indicating the document requires completion.

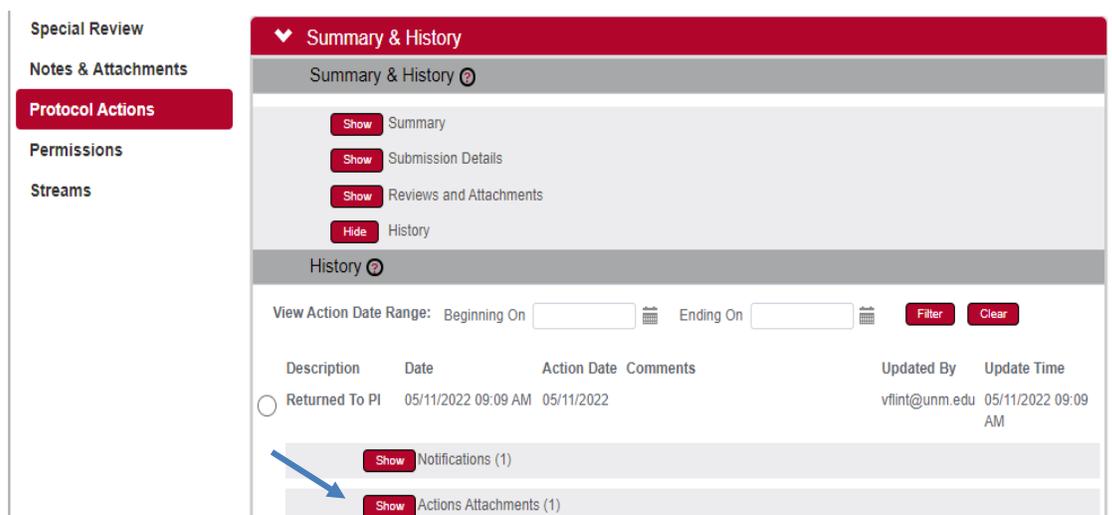
2. You can access the protocol by clicking on the hyperlink within the message body of the FYI Notification, however the quickest way to access the protocol is by clicking the hyperlinked document number in the ID column of the COM item.

COM	8198	IRB Protocol	2204002071; Geoffrey Adams
-----	------	--------------	----------------------------

3. Once in the IRB Document, click on the Protocol Actions tab: Click on Summary & History then click Show next to History



4. This will open the history information. Read the description to find **Returned to PI**. Under Returned to PI find the **Actions Attachments**. Select show next to Actions Attachments.



- To view the Return to PI to file click view in the action column.

Accessing a Protocol Returned for Revisions after IRB Review

This occurs when an IRB Administrator sends the protocol document back after at least one committee member has determined that the study cannot be approved as it is currently documented. More specifically, this occurs when one or more committee members records a determination of Specific Minor Revisions or Substantive Revisions Required.

Follow these steps when the title of the FYI Notification reads Substantive revisions requested or Specific minor revisions requested as shown in the image below:

Show	FYI	32306	Streamlyne Research Notification	Specific minor revisions requested.	FINAL	12:26 PM 02/10/2015
------	-----	-------	----------------------------------	-------------------------------------	-------	------------------------

- When revisions are specifically requested, Streamlyne will send two items to your Action List: an FYI Notification and a COM Notification, indicating the document requires completion.
- Click the Show button to open the FYI Notification.

Id: 1904
From: admin
Recipients: pedsprofessor
Channel: KC Notification Channel
Producer: Notification System
Type: FYI
Priority: Normal
Send Date: 2015-02-16T17:07:24.000-08:00
Removal Date: none

Title: Specific minor revisions requested.
Content:

The IRB protocol number [1502001123](#) has requested specific minor revisions. [view correspondence](#)

3. Streamlyne will generate a **Correspondence Letter** each time an IRB determination is recorded for a protocol. The purpose of the letter is to formally document and communicate the reason for the determination. Click the [view correspondence](#) hyperlink in the body of the message, if appropriate.
4. You may then review the reason for the determination as documented in the Correspondence. You may download and save the PDF for your records.

Note The correspondence is also stored within the protocol document. See [Accessing Correspondence](#) for more information.

5. Return to the body of the FYI Notification and click the hyperlinked protocol number to open the document.

Reviewing Reasons for the Return

There are two places that the OIRB/IRB can log comments describing the reasons for returning the protocol: in Correspondence (as shown in the previous process) and/or in Review Comments.

Accessing Review Comments

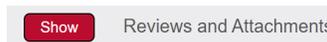
The IRB Administrator logs the reason for the return and/or the requested changes in the Review Comments subsection. Follow these steps to access this information:

1. Click on the header to access the Protocol Actions tab.
2. Click on the header to access the Summary & History section.

Protocol Actions

Summary & History

- Click on the Show button to expand the Reviews and Attachments section.



- Read through the comments to understand the changes that are required to the resubmit the study to the IRB.

Note For instructions to navigate through the tabs and sections of the protocol to perform the requested updates, see [Updating the Protocol Tab](#). When you are ready, follow the steps outlined in [Resubmitting the Protocol](#).

Accessing Correspondence

We have already seen the process to access correspondence from the FYI Notification. Follow this process to access the correspondence from within the protocol document.

- Click on the header to access the Protocol Actions tab.



- Click on the header to access the Summary & History section.



Summary & History

- Show Summary
- Show Submission Details
- Show Reviews and Attachments
- Hide History

History

View Action Date Range: Beginning On [] Ending On [] Filter Clear

Description	Date	Action Date	Comments	Updated By	Update Time
Assigned to Agenda	02/18/2022 10:39 AM	02/18/2022	Informed consent is required; documentation has been waived.	petreel@unm.edu	02/18/2022 10:39 AM
Expedited Approval	02/18/2022 10:39 AM	02/18/2022	Informed consent is required; documentation has been waived.	petreel@unm.edu	02/18/2022 10:39 AM
Correspondences (1)					
Submitted to IRB	02/18/2022 10:35 AM	02/18/2022	Submitted to IRB	gcadams@unm.edu	02/18/2022 10:35 AM
Questionnaires (1)					
Specific Minor Revisions Required	02/18/2022 10:28 AM	02/18/2022	1. Do this 2. Do that 3. Do the other 4. Please upload a new consent form	petreel@unm.edu	02/18/2022 10:28 AM
Correspondences (1)					
Notifications (1)					
Submitted to IRB	02/11/2022 10:52 AM	02/11/2022	Submitted to IRB	gcadams@unm.edu	02/11/2022 10:52 AM
Questionnaires (1)					
Returned To PI	02/11/2022 10:38 AM	02/11/2022	Please make the following corrections: 1. Upload the consent form for surveys. 2. Have Joe complete...	petreel@unm.edu	02/11/2022 10:38 AM
Notifications (1)					
Administrative Correction	02/11/2022 10:32 AM	02/11/2022	The survey attachment was misnamed.	petreel@unm.edu	02/11/2022 10:32 AM
Submitted to IRB	02/11/2022 09:00 AM	02/11/2022	Submitted to IRB	gcadams@unm.edu	02/11/2022 09:00 AM
Questionnaires (1)					
Protocol Created	02/11/2022 08:29 AM	02/11/2022	Protocol created	gcadams@unm.edu	02/11/2022 08:29 AM

Load Load selected node into Summary View, above

Copy to New Document

- Locate the most recent determination Description in the History subsection.

- Click the Show button to expand the Correspondence section to access the letter and review the reasons for the determination.

Note For instructions to navigate through the tabs and sections of the protocol to perform the requested updates, see [Updating the Protocol Tab](#).

When you are ready, follow the steps outlined in [Resubmitting the Protocol](#).

Returning Modifications to the Protocol to the IRB

- Once your changes are complete and you are ready to resubmit protocol, click on the header to access the Protocol Actions tab.



your

- Click on the header to access the Request an Action section.

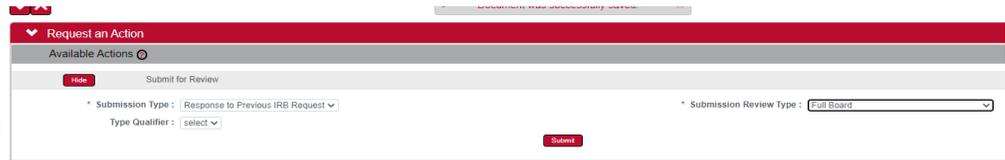


- Click on the Show button next to the Submit for Review subsection.



Submit for Review

Personnel
Questionnaire
Custom Data
Special Review
Notes & Attachments
Protocol Actions
Permissions



- Click the arrow next to the **Submission Type** field and select **Response to Previous IRB Request** from the dropdown list.

- Click the arrow next to the **Submission Review Type** field, and then select the correct value from the dropdown list.

- Click the Submit button.



Result The following updates occur:

- The Protocol Status updates to Submitted to IRB, and the Submission Status updates to Pending.
- The protocol will enter IRB workflow again as if it had been newly submitted.

Submitting Amendments & Renewals (Continuing Review)

The purpose of this section is to help you understand how to submit Amendments and Renewals with respect to the original approved protocol.

Amendment

Streamlyne allows an approved protocol to be amended at any time. The purpose of the amendment is to notify the IRB of any proposed changes to a previously approved human research study.

Renewal

Streamlyne allows an approved protocol to be renewed at any time. The purpose of the renewal is to obtain the IRB's approval to extend the study beyond the current expiration date. Streamlyne allows for both Renewals and Renewals with Amendments, as it may be necessary to amend the approved protocol at renewal time.

Starting from a Copy

When user initiates an Amendment or Renewal, Streamlyne creates the document by copying the original protocol content into a new version.

Document Number : 26792	Document Status : Amendment Incorporated into Protocol	Copied from Document Header Id : 26732
Initiator:Last Updated : crimprofessor : 03:01 PM 02/21/2018	Submission Status : Approved	
Protocol # : 1802003135A001	Expiration Date : 02/20/2019	

Streamlyne will identify the source of the copy in the Document Header, as shown above in the **Copied from Document Header ID** field.

Differences in Naming Convention

Streamlyne identifies Renewals and Amendments by appending unique identifiers to the original protocol number, following the format RNNN or ANNN respectively. For example, the Protocol # above of 1802003135A001 indicates this is the first amendment submitted for Protocol #1802003135.

Merging Amendments and Renewals

After the review process is complete, and the amendment or renewal is approved, the system versions the original protocol and merges the new information into the original document.

Streamlyne updates the Document Status to either Amendment Incorporated into Protocol or Renewal Incorporated into Protocol.

Document Status : Amendment Incorporated into Protocol

Using the Summary & History Section

When the amendment or renewal is first submitted, you can access the entire history of the project by navigating to Protocol Actions > Summary & History.

Identifying Changes in the Review Process

The screenshot shows the 'Amendment Details' section. At the top left is a 'Hide' button. The main content area has a light gray background and contains the following text:

- * **Summary:** Amendment to update the documents and modify the questionnaire
- * **Amend:**
 - General Info
 - Funding Source
 - Protocol References & Other Identifiers
 - Protocol Organizations
 - Subjects
 - Questionnaire
 - Add/Modify Notes & Attachments
 - Areas of Research
 - Special Review
 - Protocol Personnel
 - Others

For Amendments, the system will display the Amendment Details section, which contains a **Summary** of changes as well as marked sections to indicate where changes were made.

For Renewals, the system will display the Renewal Details section, which contains only the **Summary** of progress to date.

You may wish to compare to previous versions. For a quick view of the changes made to the protocol, the system will highlight all new data in red when you click the Compare to Previous Sequence button.

A button with a red 'Show' label and the text 'Compare to Previous Sequence'.

Viewing Amendments/Renewals After Approval is Granted

After the approval has been granted, the renewal and amendment information can then be viewed in the future from the Amendment/Renewal History section in Protocol Actions > Summary & History.

Click Show to view more details:

A button with a red 'Show' label and the text 'Amendment/Renewal History'.

Amendments/Renewals				
Type	Version Number	Summary	Status	Created Date
Amendment	0	Amendment to update the documents and modify the questionnaire	Amendment Incorporated into Protocol	04/20/2022
		Show Amendment Summary - 2204001644A001		
		Show Amendment Questionnaires - 2204001644A001		

Creating & Submitting an Amendment

The PI or the protocol creator can amend a protocol any time after initial approval. The review process for amendments is like the review process for initial submissions. This section will only cover the differentiators specific to creating and submitting an amendment.

The recommended way to initiate an amendment is from within the existing, active protocol: IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment.

Navigation

Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
idit copy view	2201000166	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Active - Open to Enrollment	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000166A002	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Submitted to IRB	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000166A003	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Amendment in Progress	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000175	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #2	Submitted to IRB				01/27/2022	515A	Sch of Architecture Planning SAAP	HMS	Yes
idit copy view	2202000258	1-Minimal Risk	Geoffrey C Adams	Testing Return to PI	Active - Open to Enrollment	02/23/2022	02/22/2023		02/08/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2202000334	3-IRB Review Not Required Determination	Geoffrey C Adams	TEST PROCESSING IRB	Active - Open to Enrollment	03/02/2022	03/01/2023		02/11/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2204001520	1-Minimal Risk	Geoffrey C Adams	Testing Submission Action	Pending/in Progress					515A	Sch of Architecture Planning SAAP		Yes

1. Locate the protocol that you would like to amend.
2. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to Protocol Actions > Request an Action panel. The Available Actions will display multiple options for you.

3. Click the Show button next to Create Amendment.

Show

Create Amendment

Hide

Create Amendment

* Summary:

*Amend:

General Info

Add/Modify Notes & Attachments

Funding Source

Areas of Research

Protocol References & Other Identifiers

Special Review

Protocol Organizations

Protocol Personnel

Subjects

Others

Questionnaire

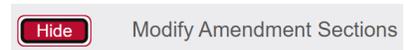
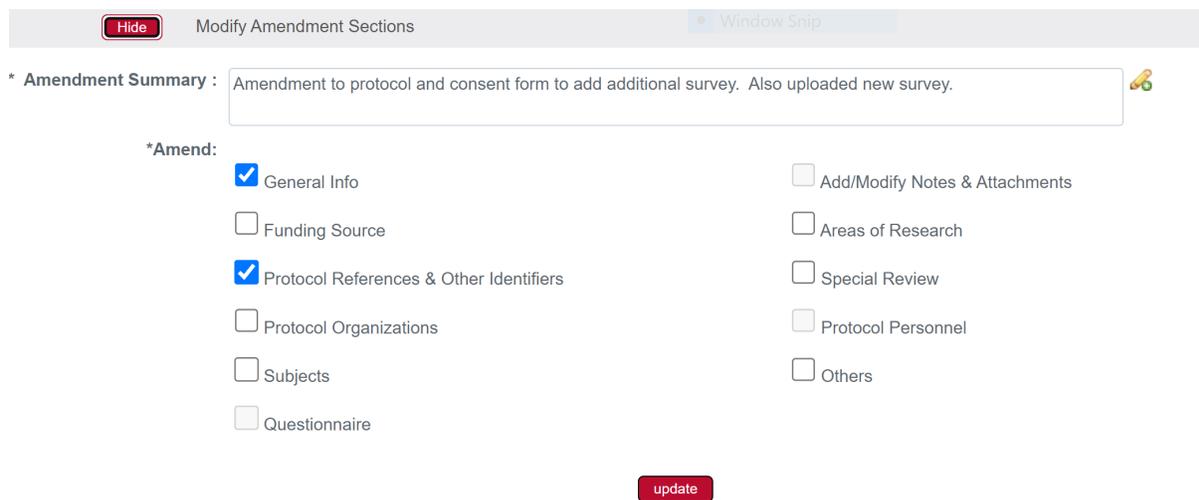
create

4. Provide a detailed description of the purpose and content of the amendment in the **Summary** field.
5. In the **Amend** section, check all boxes for sections you wish to amend. **Protocol sections with checked boxes will be opened for editing.** Those not selected will remain read-only. If making changes to any approved documents (protocol, consent form(s), recruitment materials, etc.) click on the Add/Modify Notes & Attachments box.
6. Click the Create button. 

Result Streamlyne will open a New Amendment document. You will be able to make edits in the areas you selected in Step 5.

7. If you would like to edit further sections in addition to those previously selected, navigate back to Protocol Actions > Request an Action > Available Actions.

8. Click the Show button next to Modify Amendment Sections.

* Amendment Summary :

*Amend:

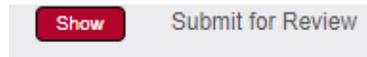
<input checked="" type="checkbox"/> General Info	<input type="checkbox"/> Add/Modify Notes & Attachments
<input type="checkbox"/> Funding Source	<input type="checkbox"/> Areas of Research
<input checked="" type="checkbox"/> Protocol References & Other Identifiers	<input type="checkbox"/> Special Review
<input type="checkbox"/> Protocol Organizations	<input type="checkbox"/> Protocol Personnel
<input type="checkbox"/> Subjects	<input type="checkbox"/> Others
<input type="checkbox"/> Questionnaire	

9. Select the applicable sections and click the Update button. 
10. Make all applicable changes to the information displayed on the protocol document as needed.

11. Click on the Questionnaire tab and complete the **Amendment Questionnaire**. You MUST complete this questionnaire before submitting the document.

12. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

13. Click the Show button next to Submit for Review.



14. Complete the required fields of **Submission Type** (e.g., Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt and Expedited (federally funded) and Minimal Risk protocols, a Checklist will display. Select all categories that apply to your study.

15. Click the Submit button  to submit your amended protocol for the required workflow approvals.

Result The delivered Data Validation routine will display any errors or warnings that pertain to this document. Be sure to complete the Questionnaire. If necessary, fix the errors and click the Submit button again to revalidate and submit.

Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32282	Document Status : Submitted to IRB	Copied from Document Header Id : 7491
Initiator:Last Updated : bioprofessor : 10:33 AM 07/18/2018	Submission Status : Pending	
Protocol # : 1501000500A001	Expiration Date : 03/17/2016	

See [Understanding Streamlyne Amendments & Renewals](#) for what Amendment details will be made available in the Summary & History section.

Creating & Submitting a Renewal (Continuing Review)

Renewals can be submitted by the PI or the protocol creator at any time after initial approval has occurred. However, the timeline for submitting a Renewal depends on both the expiration date and institutional business practices. The review process for Renewals is like the review process for initial submissions. This section will only cover the differentiators that are specific to creating and submitting a protocol for Renewal.

You can access the protocol you would like to renew through various Lookups. However, the recommended way to initiate a Renewal is through IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment or renewal.

Navigation

Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
idit copy view	2201000166	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Active - Open to Enrollment	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000166A002	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Submitted to IRB	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000166A003	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Amendment in Progress	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000175	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #2	Submitted to IRB				01/27/2022	515A	Sch of Architecture Planning SAAP	HMS	Yes
idit copy view	2202000258	1-Minimal Risk	Geoffrey C Adams	Testing Return to PI	Active - Open to Enrollment	02/23/2022	02/22/2023		02/08/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2202000334	3-IRB Review Not Required Determination	Geoffrey C Adams	TEST PROCESSING IRB	Active - Open to Enrollment	03/02/2022	03/01/2023		02/11/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2204001520	1-Minimal Risk	Geoffrey C Adams	Testing Submission Action	Pending in Progress					515A	Sch of Architecture Planning SAAP		Yes

1. Locate the protocol you wish to renew.
2. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to the Protocol Actions > Request an Action section.

3. Click the Show button next to Create Renewal without Amendment.

Show

Create Renewal without Amendment

Hide

Create Renewal without Amendment

* Summary:

create

4. Describe the progress of the project and the purpose of the renewal in the **Summary** field. If necessary, click on the edit button  to access a text editor with character count.

5. Click the Create button. 

Result This will open a new Renewal in Progress document.

6. Click on the Questionnaire tab and complete the Renewal Questionnaire. You **MUST** complete this questionnaire before submitting the document.

7. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

8. Click the Show button next to Submit for Review.  

9. Complete the required fields of **Submission Type** (e.g., Continuing Review/Continuation without Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt, Expedited and Minimal Risk protocols, a Checklist of categories will display. Select all categories that apply to your submission.

10. Click the Submit button to submit your protocol into workflow. 

Result The delivered Data Validation routine will display any errors or warnings that pertain to this document. If necessary, fix the errors and click the Submit button again to revalidate and submit.

Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32288	Document Status : Submitted to IRB	Copied from Document Header Id : 21071
Initiator:Last Updated : bioprofessor : 06:45 AM 07/19/2018	Submission Status : Pending	
Protocol # : 1701002734R001	Expiration Date : 02/05/2018	

See [Understanding Streamlyne Amendments & Renewals](#) for what Renewal details will be made available in the Summary & History section.

Creating & Submitting a Renewal with Amendment

While the system will allow a PI or the protocol creator to submit a Renewal with Amendment protocol at any time after initial approval, the timeline for submitting a Renewal depends on both the expiration date on the protocol and institutional business practices. The review process for Renewals with Amendments is similar to the review process for initial submissions. This section will only cover the differentiators that are specific to creating and submitting a protocol for both renewal and amendment.

The recommended way to initiate an amendment is from within the existing, active protocol: IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment or renewal.

Navigation
Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit	Lead Unit Name	Summary/Keywords	Active
idit copy view	2201000166	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Active - Open to Enrollment	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000166A002	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Submitted to IRB	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000166A003	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #1	Amendment in Progress	02/23/2022	02/22/2023		01/27/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2201000175	1-Minimal Risk	Geoffrey C Adams	Human Subjects Study #2	Submitted to IRB				01/27/2022	515A	Sch of Architecture Planning SAAP	HMS	Yes
idit copy view	2202000258	1-Minimal Risk	Geoffrey C Adams	Testing Return to PI	Active - Open to Enrollment	02/23/2022	02/22/2023		02/08/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2202000334	3-IRB Review Not Required Determination	Geoffrey C Adams	TEST PROCESSING IRB	Active - Open to Enrollment	03/02/2022	03/01/2023		02/11/2022	515A	Sch of Architecture Planning SAAP		Yes
idit copy view	2204001520	1-Minimal Risk	Geoffrey C Adams	Testing Submission Action	Pending/In Progress					515A	Sch of Architecture Planning SAAP		Yes

1. Locate the protocol you like to renew and amend. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to Protocol Actions > Request an Action panel. The Available Actions section will display multiple options for you.

2. Click the Show button next to Create Renewal with Amendment.

Show
Create Renewal with Amendment

Hide
Create Renewal with Amendment

* Summary:

*Amend:

General Info

Add/Modify Notes & Attachments

Funding Source

Areas of Research

Protocol References & Other Identifiers

Special Review

Protocol Organizations

Protocol Personnel

Subjects

Others

Questionnaire

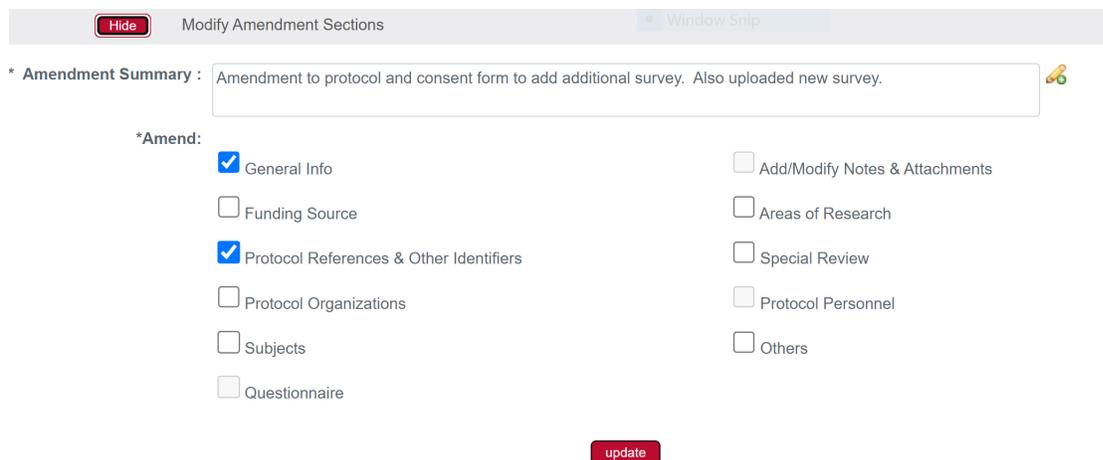
create

3. Describe the purpose and content of the amendment in the **Summary** field. If necessary, click on the edit button  to access a text editor with character count.
4. In the **Amend** section, check all boxes for sections you wish to amend. Protocol sections with checked boxes will be opened for editing. Those not selected will remain read-only.
5. Click the Create button. 

Result Streamlyne will open a new Renewal In Progress. You will be able to make edits in the areas you selected in Step 5.

6. If you would like to re-select the boxes to be able to edit further sections, navigate back to Protocol Actions > Request an Action > Available Actions.

7. Click the Show button next to Modify Amendment Sections.  Modify Amendment Sections



* Amendment Summary : 

*Amend:

<input checked="" type="checkbox"/> General Info	<input type="checkbox"/> Add/Modify Notes & Attachments
<input type="checkbox"/> Funding Source	<input type="checkbox"/> Areas of Research
<input checked="" type="checkbox"/> Protocol References & Other Identifiers	<input type="checkbox"/> Special Review
<input type="checkbox"/> Protocol Organizations	<input type="checkbox"/> Protocol Personnel
<input type="checkbox"/> Subjects	<input type="checkbox"/> Others
<input type="checkbox"/> Questionnaire	



8. Select the applicable sections and click the Update button. 
9. Make all applicable changes to the information displayed on the protocol document as needed.
10. Click on the Questionnaire tab and complete BOTH the Amendment and Renewal Questionnaires. You MUST complete these questionnaires before submitting the document.
11. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

12. Click the **Show** button next to Submit for Review.

Show

Submit for Review

13. Complete the required fields of **Submission Type** (e.g., Continuing Review/Continuation with Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt, Expedited and Minimal Risk protocols, a Checklist of categories will display. Select all categories that apply to your study.

14. Click the Submit button to submit your amended protocol for the required workflow approvals.

Submit

Result The delivered Data Validation routine will display any errors or warnings that pertain to this document. If necessary, fix the errors and click the Submit button again to revalidate and submit. Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32282

Document Status : Submitted to IRB

Copied from Document Header Id : 7490

Initiator:Last Updated : bioprofessor : 10:33 AM 07/18/2018

Submission Status : Pending

Protocol # : 1501000500A001

Expiration Date : 03/17/2016

See [Understanding Streamlyne Amendments & Renewals](#) for what details will be made available in the Summary & History section.

Communicating with the IRB

Streamlyne delivers a number of features to facilitate communication from the study team to the IRB regarding any study activity. The benefit to leveraging these features is that all communication will be captured in the Summary and History sections of the protocol. This chapter will review the purpose of each of these features, and provides the steps to execute each.

Notifying the IRB

This process applies to all instances in which the PI needs to notify the IRB Committee of an event that occurred that may require further review or scrutiny by an IRB Administrator and/or IRB Committee. The most common occurrences are adverse events, unanticipated problems or protocol deviations. However, there are a variety of events that may be applicable. Not all will be covered in this manual, but the steps to submit a Notify IRB action are the same.

Access the protocol through IRB Actions > Notify the IRB on a Protocol. Clicking this menu option will display all the protocols that qualify for this action.

Navigation

Main Menu > IRB > IRB Actions > Notify IRB on a Protocol

This function is used to notify the IRB and provide information when reporting certain items. These include:

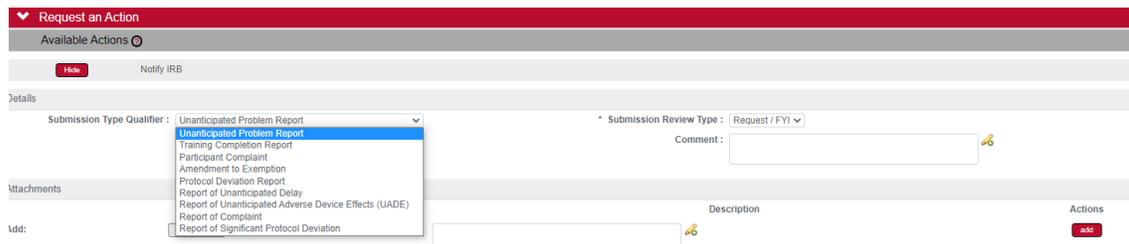
- Training certification,
- Adverse Event Reporting,
- Unanticipated Problem Reporting,
- Participant Complaint reporting,
- Amendment to Exempt study,
- Protocol Deviation Report,
- Post Approval Monitoring Response.

1. Locate the protocol that you would like to notify the IRB about.
2. Click the perform action hyperlink on the corresponding row.

Result This will open the protocol on the Protocol Actions > Request an Action > Available Actions subsection.

Note You may alternatively navigate to Protocol Actions > Request an Action > Available Actions subsection, if you are already in the protocol for which you would like to take action.

3. Under Available Actions, the Notify IRB section will display.



4. In the **Submission Type Qualifier** field, use the dropdown to select the appropriate option.

Note **Submission Review Type** will default to FYI and cannot be changed.

5. In the **Comment** field, enter freeform text regarding the reason for the notification.

6. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.

7. In the **Description** field enter a description of the attachment if needed.

8. Click the add button. 

9. Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Notify IRB action. 

Result A notification and attachments if present will go to the OIRB and/or IRB Committee for review as applicable to the event. You may not have any available Actions while your request is being processed.

Note Once the review is complete, the user should receive a response indicating that the IRB has acknowledged the event. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before full acknowledgment takes place.

Requesting to Close a Protocol

PI's are required to formally close protocols once the research is complete, is no longer being executed, or the PI is transferring to a different institution.

Navigation

Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol you would like to close and click on the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

2. Navigate to Protocol Actions > Request an Action > Available Actions.

3. Click the Show button next to Request to Close.



4. In the **Reason** field, enter freeform text to describe the reason you would like to close the protocol.

5. In the Attachments subsection, upload a Closure Report by clicking the Browse button and following your operating system's prompts, if needed.

6. In the **Description** field enter a description of the attachment if needed.

7. Click the add button.



Notes Repeat Steps 7 through 9 until all necessary attachments are added.

- Click the Submit button to finalize the Request to Close action.



Result The request and supplemental information will go to the OIRB for review as applicable.

Note Once the OIRB has received the Request to Close and the request has been approved, the user should receive a response indicating that your protocol has officially been closed. The format of the response and any accompanying correspondence will be based on your institution’s workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Suspend a Protocol

Your institution may require PI’s to formally request to suspend a protocol. A PI may wish to pause a study for a variety of reasons, however, the steps to request a suspension are the same regardless of reason or previous actions taken on the protocol.

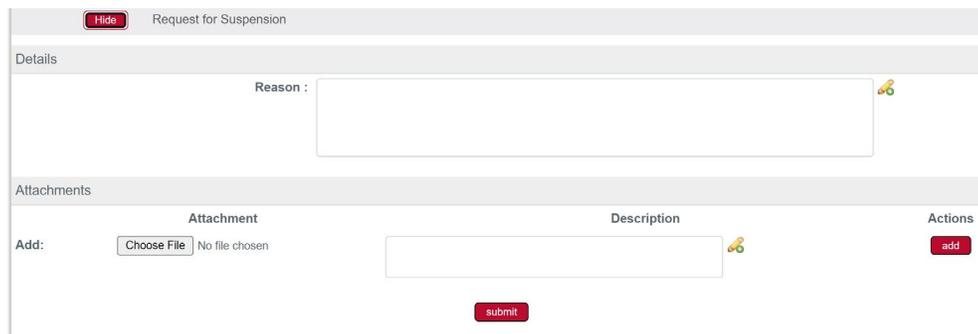
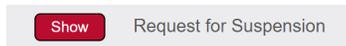
Navigation Main Menu > IRB > IRB Lookups > All My Protocols

- Locate the protocol you would like to suspend.
- Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

- Navigate to Protocol Actions > Request an Action > Available Actions.

- Click the Show button next to Request for Suspension.



The form is titled "Request for Suspension" and has a "Hide" button in the top left corner. It is divided into two main sections: "Details" and "Attachments".

Details: This section contains a "Reason:" label followed by a large text input field. To the right of the input field is a small icon representing a document with a checkmark.

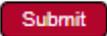
Attachments: This section has a table-like structure with columns for "Attachment" and "Description".

- Under "Attachment", there is an "Add:" label, a "Choose File" button, and the text "No file chosen".
- Under "Description", there is a text input field and a small icon representing a document with a checkmark.
- Under "Actions", there is a red "add" button.

At the bottom center of the form is a red "submit" button.

5. In the **Reason** field, enter freeform text to describe the reason you would like to suspend the protocol.
6. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
7. In the **Description** field enter a description of the attachment if needed.
8. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

9. Click the Submit button to finalize the Request for Suspension action. 

Result The request and supplemental information will go to the OIRB and/or IRB Committee review as applicable.

Note Once the OIRB has received the Request for Suspension and the request has been approved, the user should receive a response indicating that your protocol has officially been suspended. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Close Enrollment on a Protocol

Your institution may require PI's to formally request to close enrollment of subjects for your protocol. This will occur once you are no longer actively recruiting research subjects for your protocol.

Navigation

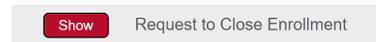
Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol where you would like to close enrollment and click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

2. Navigate to Protocol Actions > Request an Action > Available Actions.

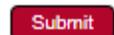
3. Click the Show button next to Request to Close Enrollment.



4. In the **Reason** field, enter freeform text to describe the reason you would like to close enrollment on the protocol.
5. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
6. In the **Description** field enter a description of the attachment if needed.
7. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

8. Click the Submit button to finalize the Request to Close Enrollment action.



Result The request and supplemental information will go to the OIRB and/or IRB Committee review as applicable.

Note Once the OIRB has received the Request to Close Enrollment and the request has been approved, the user should receive a response indicating that your protocol has officially been closed for enrollment of subjects. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

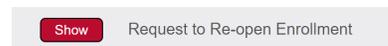
Requesting to Re-Open Enrollment on a Protocol

PIs are required to formally request to re-open enrollment of subjects for your protocol. This request will only be available if the current status of your protocol is Active-Closed to Enrollment.

1. Locate the protocol where would like to re-open enrollment.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.
4. Click the Show button next to Request to Re-open Enrollment.



The screenshot shows a web form titled "Request to Close Enrollment". At the top left, there is a "Hide" button. Below the title is a "Details" section containing a "Reason" label followed by a large text input field. Below this is an "Attachments" section with a table. The table has columns for "Attachment", "Description", and "Actions". Under "Attachment", there is an "Add:" label, a "Choose File" button, and the text "No file chosen". Under "Description", there is a text input field. Under "Actions", there is an "add" button. At the bottom of the form, there is a "submit" button.

5. Do not select a Committee.
6. In the **Reason** field, enter freeform text to describe the reason you would like to re-open enrollment on the protocol.
7. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
8. In the **Description** field enter a description of the attachment if needed.
9. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

10. Click the Submit button to finalize the Request to Re-open Enrollment action.



Result The request and supplemental information will go to the OIRB and/or IRB Committee review as applicable.

Note Once the OIRB has received the Request to Re-open Enrollment and the request has been approved, the user should receive a response indicating that your protocol has officially been re-opened for enrollment of subjects. The format of the response and any accompanying correspondence will be based on your institution’s workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Identify a Protocol in a Data Analysis Only Phase

Your institution may require PI’s to formally request to transition a study into a data analysis only phase when you reach that point in the study. This will occur when only data analysis is being conducted and data collection and interaction with human subjects has ceased.

Navigation	Main Menu > IRB > IRB Lookups > All My Protocols
-------------------	--

1. Locate the protocol where you would like to request a data analysis only phase.
2. Click the edit hyperlink on the corresponding row.

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

3. Navigate to Protocol Actions > Request an Action > Available Actions.

4. Click the Show button next to Request for Data Analysis Only.

Show	Request for Data Analysis Only
------	--------------------------------

Hide Request for Data Analysis Only

Details

Reason :

Attachments

	Attachment	Description	Actions
Add:	<input type="button" value="Choose File"/> No file chosen	<input style="width: 100%; height: 30px;" type="text"/>	<input style="background-color: #c00000; color: white; padding: 2px 5px; border-radius: 3px;" type="button" value="add"/>

5. In the **Reason** field, enter freeform text to describe the reason you would like to transition the protocol to a data analysis only phase.
6. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.
7. In the **Description** field enter a description of the attachment if needed.
8. Click the add button. 

Notes Repeat Steps 7 through 9 until all necessary attachments are added.

9. Click the Submit button to finalize the Request for Data Analysis Only action. 

Result The request and supplemental information will go to the OIRB and/or IRB Committee review as applicable.

Note Once the OIRB has received the Request for Data Analysis Only and the request has been approved, the user should receive a response indicating that your protocol has officially transitioned to a data analysis only phase. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Requesting to Terminate a Protocol

Your institution may require PI's to formally request to terminate the study. This action can occur for a variety of reasons, however, the steps to request a termination are the same regardless of reason or previous actions taken on the protocol.

Navigation

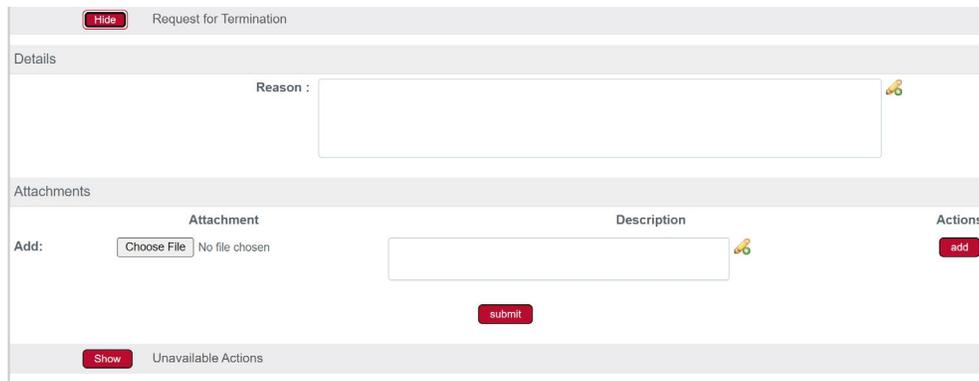
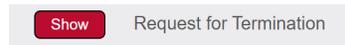
Main Menu > IRB > IRB Lookups > All My Protocols

1. Locate the protocol you would like to terminate and click the edit hyperlink on the corresponding row

Result This will open the protocol so only the Available Actions section is available for editing. The remainder of the protocol is in a view-only state.

2. Navigate to Protocol Actions > Request an Action > Available Actions.

3. Click the Show button next to Request for Termination.



4. In the **Reason** field, enter freeform text to describe the reason you would like to terminate the protocol.

5. In the Attachments subsection, upload an attachment by clicking the Browse button and following your operating system's prompts if needed.

6. In the **Description** field enter a description of the attachment if needed.

7. Click the add button.



Notes Repeat Steps 7 through 9 until all necessary attachments are added.

8. Click the Submit button to finalize the Request for Termination action.



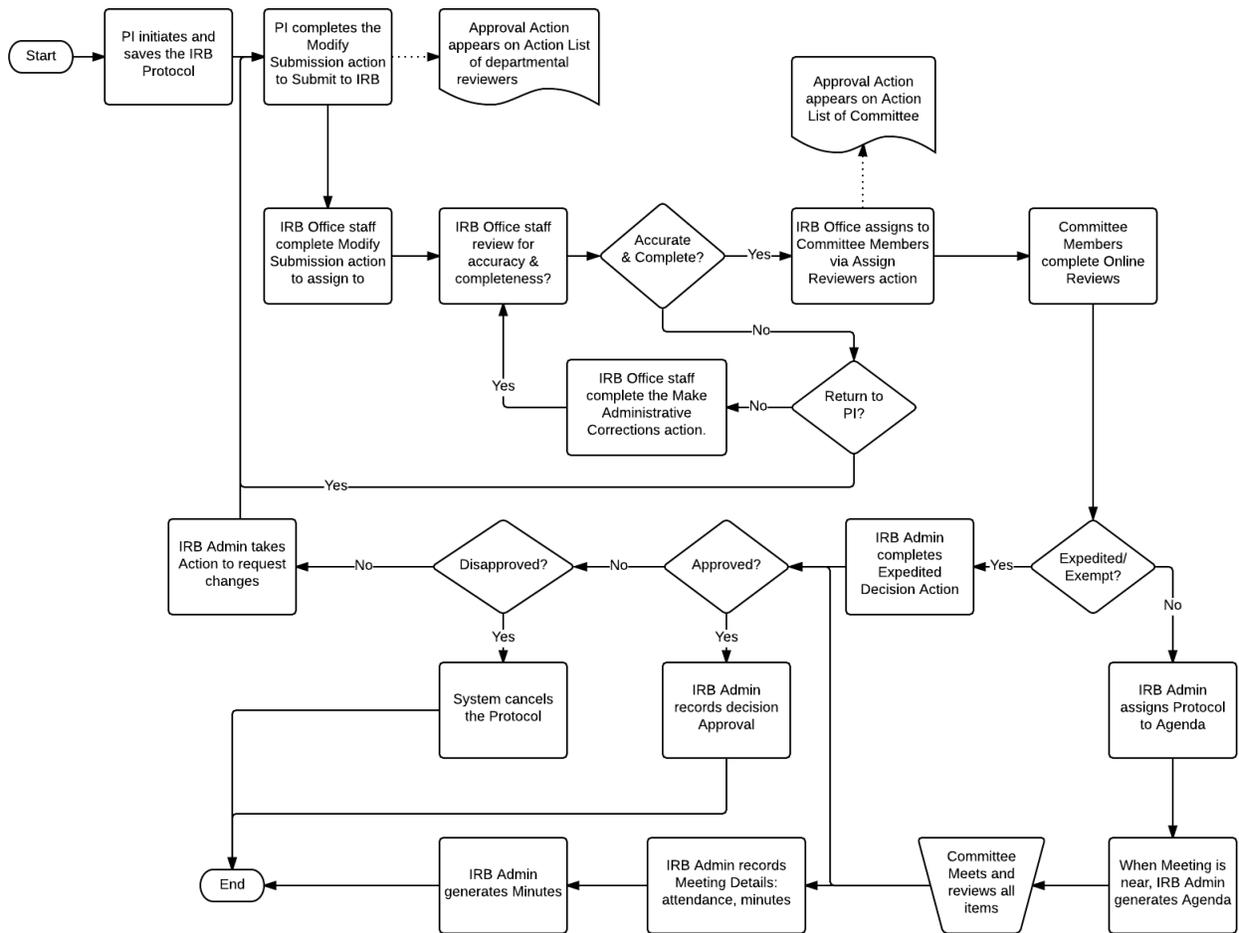
Result The request and supplemental information will go to the OIRB office and/or IRB Committee review as applicable.

Note Once the OIRB has received the Request for Termination and the request has been approved, the user should receive a response indicating that your protocol has been terminated. The format of the response and any accompanying correspondence will be based on your institution's workflow configuration. It may display as an FYI in your Action List. You can always access this information in Protocol Actions>Summary & History. The IRB may request further information before this action takes place.

Appendix A: IRB Roles and Permissions

Role	IRB Protocol Permissions
Protocol Viewer	Ability to view IRB protocols with read-only privileges
Protocol Creator	Ability to initiate IRB protocol documents
Protocol Aggregator	Ability to edit IRB protocol documents

Appendix B: IRB Protocol Workflow Overview



Appendix C: Investigator IRB Protocol Actions

Action	Role	Description	Prerequisites	Result
Abandon	Investigator	Used to cancel a protocol that has been returned for revisions by IRB Administrators or Reviewers, but the PI no longer intends to pursue the study.	Both Submission Status and Protocol Status must be one of the following: Specific Minor Revisions, Substantive Revisions Required.	Protocol Status is updated to Abandoned.
Create Amendment	Investigator	Used to request an amendment to a previously approved protocol, incorporating minor administrative changes through changes to study design.	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Protocol Status updates to be Amendment in Progress.
Create Renewal with Amendment	Investigator	Used to both renew a protocol set to expire, AND to incorporate various changes to the protocol. (See also: Create Renewal without Amendment and Create Amendment)	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Protocol Status updates to Renewal in Progress.

Action	Role	Description	Prerequisites	Result
Create Renewal without Amendment	Investigator	Used to renew a protocol set to expire when no changes need to be incorporated.	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Expired, Closed Administratively (for lack of response), Closed by Investigator, Suspended by Investigator, Suspended by IRB.	Protocol Status updates to Renewal in Progress.
Delete Protocol, Amendment or Renewal	Investigator	Used to delete a protocol, amendment, or renewal prior to submission, because the PI no longer intends to pursue the study.	Protocol Status must be one of the following: Pending/In Progress, Renewal In Progress, Amendment in Progress.	Protocol Status updates to Deleted. Protocol is marked as Inactive, and therefore will only appear in search results for Inactive documents.
Manage Notes	Investigator and IRB Admin	Used to add and edit notes associated with a protocol. Administrators cannot edit Investigator notes, but Administrators can control visibility using the restricted checkbox.	None.	Notes are updated.

Action	Role	Description	Prerequisites	Result
Modify Amendment Sections	Investigator	Used to modify specified sections for amendment when submitting an Amendment or Renewal with Amendments.	Protocol Status must be Amendment in Progress or Renewal in Progress.	Amendment sections are updated.
Notify IRB	Investigator	Used to inform the IRB of an event or change that may not require committee review.	Protocol Status must be one of the following: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Suspended by Investigator, Suspended by IRB, Withdrawn, Suspended by DSMB, Expired, Disapproved, Terminated by IRB, Suspended by IRB, Suspended by DSMB.	Submission Status updates to Submitted to IRB or Pending.
Request for Data Analysis Only	Investigator	Used to notify the committee that the study has entered a phase where only data analysis is being conducted. Data collection and interaction with human subjects has ceased.	Protocol Status must be Active-Open to Enrollment or Active-Closed to Enrollment.	Submission Status updates to Pending.

Action	Role	Description	Prerequisites	Result
Request for Suspension	Investigator	Used to request suspension of an active protocol, usually when researchers have identified new risks that require investigation before proceeding. (See also: Suspend)	Protocol Status must be in one of the following statuses: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt.	Submission Status updates to Pending.
Request for Termination	Investigator	Used to request termination of protocol, usually when researchers have determined that it is no longer safe to continue. (See also: Terminate)	Protocol Status must be in one of the following statuses: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Suspended by Investigator, Suspended by IRB.	Submission Status updates to Pending.
Request to Close	Investigator	Used to request protocol closure when all activities pertaining to the study are complete. (See also: Close)	Protocol Status must be in one of the following statuses: Active-Open to Enrollment, Active-Closed to Enrollment, Active-Data Analysis Only, Exempt, Suspended by Investigator, Suspended by IRB.	Submission Status updates to Pending.

Action	Role	Description	Prerequisites	Result
Request to Close Enrollment	Investigator	Used to request that enrollment on a study be formally closed, as no new human subjects will be enrolled for participation on an active protocol. (See also: Close Enrollment)	Protocol Status must be Active-Open to Enrollment.	Submission Status updates to Pending.
Request to Reopen Enrollment	Investigator	Used to request that the enrollment of human subjects is reopened on a study after having been closed for a period of time. (See also: Reopen Enrollment)	Protocol Status must be Active-Closed to Enrollment.	Submission Status updates to Pending.
Submit for Review	Investigator	Used to submit a protocol, amendment, or renewal to the IRB for review.	Protocol status must be In Progress, Specific Minor Revision Required, Substantive Revision Required, Amendment In Progress, Renewal In Progress, Deferred, or Withdrawn.	Protocol Status updates to Submitted to IRB. Submission Status updates to Pending.